

II. Rejections under 35 U.S.C. §112, second paragraph

Claims 29 and 36 stand rejected under 35 U.S.C. §112, second paragraph due to a couple of informalities. These informalities have been corrected by the foregoing amendments. These amendments have been made solely for purposes of correcting informalities and do not affect the scope of the claims.

According to the Office Action, claim 29 is dependent on a canceled claim. Applicant has rewritten claim 29 in independent form to include substantially all of the limitations of canceled claim 27.

According to the Office Action, in claim 36 the limitation "the position of the tool" lacks antecedent basis. Applicant has amended claim 36 by replacing "the" with --a--.

In view of the above, Applicant requests withdrawal of the rejection of claims 29 and 36 under 35 U.S.C. §112, second paragraph.

III. Rejections Under 35 U.S.C. §103

Claim 36 stands rejected under 35 U.S.C. §103(a) as being unpatentable over *Manwaring* in view of *Yabe*. According to the Examiner, *Yabe* teaches "an endoscope system for getting biopsy information in which the endoscope includes a monitor for displaying live video images". Therefore, according to the Office action, "it would have been obvious to one of ordinary skill in the art at the time the invention was made to use the endoscope of *Yabe* with the system of *Manwaring et al.* to allow the information regarding the position, orientation, and trajectory of the endoscope be displayed on the endoscope itself.

Applicant respectfully traverses this rejection. The Examiner admits that *Manwaring* makes no suggestion of the desirability of placing a navigation display on the tool, but provides no reasoning as to how the existence of an endoscope that displays certain patient information suggests modifying of *Manwaring's* guidance system to display on a probe instead of on a remote monitor navigational directions for moving the probe to a desired location. It is respectfully submitted that the Examiner's

reasoning is legally insufficient to establish a *prima facie* case of obviousness (i) for this reason and (ii) for the reasons noted below.

First, the Examiner admits that *Manwaring* does not teach that mounting a display on a probe.

Second, as understood, the purpose of *Yaba's* system is to help a doctor remember where he has been (see Col. 1, lines 5-22) – not to help him navigate where to go. *Yabe* teaches a biopsy information recording apparatus that records information on biopsies. The displayed image in *Yabe* comprises a still picture frame along with examination serial number, patient's name, patient's number, and examination date. See Figure 5 of *Yabe*. It submitted *Yabe* assumes that the endoscope is in the desired position before taking a picture and does not suggest a need for displaying differences between the position and the desired position of the tool. There is no indication or suggestion in *Yabe* for modifying it to indicate the position of the endoscopic tool relative to a desired position of the endoscope. It is submitted that a mere display of a still picture of the cavity does not suggest or teach “a display ... for indicating differences between the position of the tool and the desired position of the tool.”

Third, it seems that the Examiner may be suggesting that the prior art could have been modified in the manner taught by the claims, and thus the claimed invention is obvious. However, obviousness cannot be established based on the fact that a modification can be made. As the Court of Appeals for the Federal Circuit has stated,

The mere fact that the prior art may be modified in the manner suggested by the examiner does not make the modification obvious unless the prior art suggested the desirability of the modification. *In re Fritch*, 972 F.2d 1260, 23 U.S.P.Q.2d 1780, 1783-84 (Fed. Cir. 1992)

The Examiner has not identified any desirability for making the modification. Indeed, as already submitted, *Manwaring* and *Yabe* do not contain any such teaching.

Finally, the only teaching appears to be Applicant's own specification. As explained, on page 2, lines 1 to 13 of the present application,

Although image guided surgery systems are more accurate and provide the surgeon with more information compared to previous techniques, it is sometimes difficult to

visualize, with reference to image data displayed on the monitor, the manipulation required to place the surgical tool in the desired position and orientation. As will be appreciated, the surgeon is required to visualize the position of the tool with respect to the image data and then relate that information to a required motion of the tool in relation to the patient. . . . Accordingly, it would be desirable to provide the surgeon with a readily understandable indication of the proper tool position and orientation without requiring the surgeon to divert his or her attention to a remote monitor or display.

Thus, a surgeon may be guided to move the tool to a desired position based on the display which is on the tool itself. Thus, the rejection can only be based on impermissible application of hindsight.

For these reasons, it is respectfully submitted that the rejection is in error.

IV. New Claims 37-40

New claims 37-40 have been added for purposes of defining the invention in a different way, and are not being submitted to overcome the prior art rejections noted above. These claims add no new matter to the application and are supported in the specification as originally filed, for example, on page 3, lines 19-27 and page 6, lines 24-26. Applicant submits that these new claims are allowable for at least the same reasons that independent claim 36 is allowable.

CONCLUSION

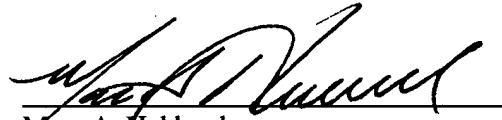
It is submitted that the application is in condition for allowance. Such action is respectfully requested. Please telephone the undersigned representative should he be of any assistance.

Applicants submit herewith a Fee Transmittal for the addition of claims and a Petition for Extension of Time under 37 C.F.R. §1.136(a).

The Commissioner is hereby authorized to charge any fees or credit any overpayment associated with this Amendment to Deposit Account No. 13-4900 of Munsch Hardt Kopf & Harr, P.C.

Respectfully submitted,

Date: June 20, 2001
Munsch Hardt Kopf & Harr, P.C.
1445 Ross Avenue, Suite 4000
Dallas, TX 75202
Tel. (214) 855-7571
Customer No. 23559



Marc A. Hubbard
Registration No. 32,506

VERSION WITH MARKINGS TO SHOW CHANGES MADE

In the Claims:

Claim 29 has been amended as follows:

29. (Twice Amended) [The method of claim 27 wherein the step of indicating the distance comprises the step of] A method for guiding the movement of a surgical tool with respect to the anatomy of a patient having a patient reference frame, the method comprising the steps of:
displaying an image of the anatomy of the patient on a display disposed remote from the surgical tool;
determining a desired position of the tool based on the displayed image;
determining a direction the tool must be moved to reach a desired position;
determining an actual position of a position indicator having an indicator reference frame,
wherein the position indicator is mounted to the tool and the step of determining an actual position of the position indicator includes determining an actual position of the tool; and
utilizing the position indicator to indicate to a human the magnitude of the distance the tool must be moved to reach the desired position, said indication being provided in relation to the indicator reference frame, wherein said indication is provided by varying the one of the blink rate and color of an indicator visible to a user.

Claim 36 has been amended as follows:

36. (Once Amended) An apparatus comprising:
a tool for use in connection with surgery[.];
means for determining [the] a position of the tool relative to a desired position of the tool[.];
and
a display disposed on the tool for indicating differences between the position of the tool and the desired position of the tool.

Please add new claims 37-40 as follows:

37. (New) An apparatus, comprising:
a surgical tool;
means for determining a position of the surgical tool; and
a display mounted on the surgical tool for visually indicating a direction in which the display should be moved for the surgical tool to reach a desired position.

38. (New) The apparatus of claim 37, wherein the display includes a plurality of position indicators disposed at angular intervals so as to surround a central point.

39. (New) A method for guiding the movement of a surgical tool, said method comprising:
tracking a surgical tool with reference to a patient's anatomy;
determining a direction in which said surgical tool must be moved from an actual position to reach a desired position with respect to the patient, the desired position being indicated with reference to a diagnostic image of the patient; and
indicating on a display disposed on said surgical tool the direction in which the tool must be moved from said actual position to reach said desired position, wherein said indication is provided with reference to a reference frame of said surgical tool.

40. (New) The method of claim 39, wherein said tool reference frame is defined such that the origin of said tool reference frame is at the tip of said surgical tool, wherein said tool reference frame has an axis substantially collinear with a pointing axis of said surgical tool.